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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,025	10/10/2001	Geert Maertens	2752-56	7266

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,025	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *100-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 100-118 are pending.

Response to Amendment

This is a response to the amendment, paper No. 14, filed 09/12/03. Claims 1-99 have been canceled. Claims 100-118 have been added. Claim 100-118 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 100-104, 107-112 and 116-117 are rejected under 35 U.S.C. 102(a) as being anticipated by Mehta et al. (Patent No. 5,308,750A) on the same ground as stated in the previous Office Action because they read on the same scope of rejected claims 49 and 54.

3. Applicants traverse the rejection and submitted that Mehta et al. at best describes a monoclonal antibody which react with an epitope spanning amino acids 649-655 of the E2 region, The monoclonal antibodies of the presently claimed invention are therefore, not taught or suggested by Mehta et al.

4. Applicants' argument has been fully considered; however, it is not found persuasive because Mehta et al. disclose the isolated antibody reacts with six amino acids sequences, which are amino acids from 600-720 (SEQ ID NO: 1) (line 35 on col. 10), 607-627 (SEQ ID NO: 2), 643-663 (SEQ ID NO: 3), 666-683 (SEQ ID NO: 4), 671-691 (SEQ ID NO: 5) (lines 267-45 on col. 11) and 643-683 (SEQ ID NO: 6), whereas the claims 100-104, 107-112 and 116-117 are directed to a monoclonal antibody binds to at least one region within a domain disclosed by Mehta et al. (See line 30 on col. 10 to line 45 on col. 11). For example, the region of amino acids

666-683 or 671-691 in the domain of amino acid segment of 655-809 of claim 100. Therefore, the rejection is still maintained.

5. Regarding Claims 101-104, 107-112 and 117, they belong to the product-by-process type of claims. According to MPEP of product-by -process claims in chapter 2100: even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113.

6. Regarding to the limitation of claim 116, because the antibody disclosed by prior art raised against same epitope of the HCV E1 and/or E2, it inherently recognized same epitope of the HCV envelope as it is claimed.

7. Applicants are also reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. **See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) [PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical.] Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows: Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].** Therefore, in this context, the cited prior art inherently anticipated the claims.

8. In the instance case, the patenbility of a monoclonal antibody is only depended on the epitope to which the claimed monoclonal antibody recognizes. Therefore, claims 101-104, 107-112 and 116-117 are also anticipated by the cited reference.

New Ground Rejection:

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 100- 113, 115 and 117-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Leys et al. (WO 93/180542) and Matsuura et al. (J. Virol. 1992, 66, No. 3, pp. 1425-1431).

11. The claimed invention is directed to a monoclonal antibody raised against the amino acid segment of HCV E2, wherein the amino acid segment is selected from the amino acid residues from 397-416.

12. De Leyes et al. disclose a peptide comprising the segment having a 100% homology to the amino acid residues 397-416 of SEQ ID NO: 72. De Leyes et al. did not claim a monoclonal antibody raised against this fragment; however, De Leyes et al. teach that this peptide can be used as an immunogenic composition for inducing an immune response in the host. Rosa et al. do not teach to use vaccinia virus or yeast to produce the envelope protein.

13. Matsuura et al. disclose a method for producing a recombinant envelope glycoprotein E1 and/or E2 in mammalian cell lines with vaccinia virus encoding a HCV envelope protein as well as yeast, Saccharomyces cerevisae transfected with a plasmid comprising a HCV envelope protein (see section of MATERIALS AND METHODS on pages 142501426).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited reference of De Leyes et al. to generate a monoclonal antibody by adapting the method disclosed by Matsuura et al. without unexpected results because it is well known in the art that an injection of any antigenic peptide or polypeptide will induce an antibody production as long as the peptide of polypeptide is approved to be immunogenic. At this point, since De Leys et al. have already approved that the peptide

having 100% homology to the peptide of SEQ ID NO: 72, which is an immunogenic and Rosa et al teach to the envelope protein expressed by either vaccinia virus or yeast, the ordinary skill person in the art will be able to use the peptide expressed by the vaccinia virus or yeast to generate monoclonal antibody absence of unpredictable results. Regarding to the limitation of claim 113, because the antibody raised from he peptide disclosed by De Leyes et al. has a overlapping sequence with amino acid residues 397-415, it will competent with the monoclonal antibody raised from the peptide 397-416.

15. Regarding to the limitation of 107-112, because claims are directed to the envelope protein purified at least 90-99% pure; the prior art teaches that the E2 protein is purified, which include the ranges at least 90 to 99%. Therefore, it still anticipates the claims.

16. Regarding to claims 106 and 118, because the major component of the kit is the monoclonal antibody, the package of an isolated monoclonal antibody in a kit would be routine work for a person with ordinary skill in the art.

17. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

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18. Claim 114 is free of prior art. However it is not in allowable condition because it is depended on the rejected claim 100.

Conclusion

No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

December 08, 2003

JAMES HOUSEL 12/5/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600